2. RESPONSE/REMARKS

2.1 STATUS OF THE CLAIMS

Claims 1-12 and 21-40 were pending at the time of the Action.

Claim 22 has been amended herein.

Claims 1-12 and 21-40 remain pending in the application.

Applicants respectfully request reconsideration of the remarks herein, removal of all outstanding claim objections and rejections, and allowance of all pending claims.

2.2 SUPPORT FOR THE PENDING CLAIMS

Support for the pending claims can be found throughout the original claims, specification and figures as filed. It will be understood that no new matter is included within amended claim 22.

2.3 A SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IS PROVIDED

Applicants respectfully request entry and consideration of the Information Disclosure Statement Provided herewith.

2.4 THE OBJECTION TO CLAIM 22 IS OVERCOME

The Action at page 3 objected to claim 22 under 37 C. F. R. § 1.75(c), allegedly as being of improper dependent form.

Applicants appreciate the Examiner's observation of the unintentional clerical error in claim 22. Applicants have amended claim 22 to recite "...administration to a human brain,"

which Applicants believe properly overcomes the objection. Applicants respectfully request, therefore, that the objection be withdrawn in light of the present amendment.

2.5 THE REJECTIONS OF CLAIMS UNDER 35 U. S. C. §103(A) ARE OVERCOME

The Action at page 5 rejected claims 1, 2, 4-7, 10-12, 21-38 and 40 under 35 U. S. C. §103(a), allegedly as being legally obvious in view of Pritchard* et al., *(J. Endocrinol., 172:411-42, 2003)(hereinafter, "Pritchard") when taken together with Wilson* et al., *(PCT Intl. Pat. Appl. Publ. No. WO/2000/28061) (hereinafter "Wilson").

The Action at page 9 rejected claims 1, 2, 4-12, 21-38 and 40 under 35 U. S. C. §103(a), allegedly as being legally obvious in view of Pritchard and Wilson further in view of Lasic* et al. *(Tibtech, 16:307-321, 1998) (hereinafter "Lasic").

The Action at page 10 rejected claims 1-7, 10-12 and 21-40 under 35 U. S. C. §103(a), allegedly as being legally obvious in view of Pritchard and Wilson, in view of Paterna* et al. *(Gene Ther., 7:1304-1311, 2000) (hereinafter "Paterna2"[1]).

With respect to each rejection, Applicants again respectfully traverse.

In order to sustain a rejection of obviousness, the Office must demonstrate that combining or modifying the teachings of the prior art to produce the claimed invention is from some teaching, suggestion or motivation to do so *found in the references themselves or in knowledge generally available to those practiced in the art*, see *In re Fine*, 837 F.2d 1071, 1988; *In re Jones*, 958 F. 2d 347, 1992. Even if one could, *arguendo*, combine the references, there must be a specific motivation in the references themselves, to produce the combination, see *In re Mills*, 916 F.2d 6080, 1990.

[1]To distinguish the present Paterna reference from the Paterna *et al.*, reference cited in previous office actions (*Methods*, **28**:208-218, 2002).

A finding of obviousness under 35 U. S. C. § 103(a) requires a determination of the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed subject matter and the prior art, and whether the differences are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere*, 383 U.S. 1, 148 USPQ 459 (S. Ct. 1966).

The relevant inquiry is whether the prior art suggests the invention and whether the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell*, 7 USPQ2d 1673 (Fed. Cir. 1988). Both the suggestion *and* the reasonable expectation of success must be founded in the prior art and not in Applicants' patent Specification. *In re Vaeck*, 20 USPQ 1438 (Fed. Cir. 1991).

Applicants respectfully request the Examiner's application of the standard set forth in *In re Vaeck*, 20 U.S.P.Q. 1438 (Fed. Cir. 1991), wherein the Federal Circuit concluded that in order for a patent Examiner to make out a *prima facie* case of obviousness *two* things must be shown:

> (1) That the prior art would have suggested to those of ordinary skill in the art that they should make the claimed invention; and
>
> (2) That the prior art must demonstrate a reasonable expectation of success of the invention.

Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the Applicant's disclosure (emphasis added).

Furthermore, in the case of *In re* Dow Chemical Co. (837 F. 2d 469, 5, U.S.P.Q.2d 1529, Fed. Cir. 1988) the court held that an "obvious-to-experiment" standard is not an acceptable alternative for obviousness, and that there must be a reason or suggestion in the art, *other than* the knowledge learned from the Applicants' disclosure.

In the instant case, however, there is neither the suggestion nor the reasonable expectation of success. Even if one could somehow postulate that one or more of the cited references might suggest that the methods disclosed in the present application might, in an abstract sense, be *plausible*, there is certainly no teaching or suggestion as to how one would go about developing the particular rAAV-delivered POMC constructs of the present invention, nor is there any suggestion in the cited references, either alone or in combination, that such an approach would be successful. These references (either alone or in any combination) do not provide the motivation or the teaching for preparing rAAV-POMC genetic constructs, or for using such constructs (or viral particles comprising such vectors) using the novel and non-obvious methods claimed herein, and likewise there is no motivation or teaching that such methods would be useful to achieve an improved method for long-term neurological activity *via* a viral vector-based gene therapy approach.

Furthermore, Applicants submit that the combination of references relied upon by the Examiner also clearly fails to satisfy the tripartite test of *In re O'Farrell* (7 U.S.P.Q.2d 1673, 1680, Fed. Cir. 1988). In *O'Farrell*, the Court held that in order for a reference or references to obviate an invention, it must be shown that the reference(s) contains:

(1) Detailed enabling methodology for practicing the claimed invention;

(2) A suggestion for modifying the prior art to practice the claimed invention; and

(3) Evidence suggesting that the invention would be successful.

In the instant Application, however, *none* of the cited references provides any teaching relevant to the question of how one of skill would arrive at the rAAV-POMC vector compositions, or the methods for making such genetic constructs as disclosed in the present application. The cited references most certainly do not provide any "detailed enabling methodology" for using the claimed rAAV-POMC compositions, particularly in the long-term treatment of mammalian

obesity. Moreover, the cited references fail to provide a suggestion for combining the teachings of the individual references or for modifying either or all of the references in a manner that would allow one to achieve the present invention. Lastly, no combination of the four cited references provides sufficient evidence that the rAAV-POMC-based genetic constructs could be successfully used in providing therapeutic amounts of POMC polypeptides to a mammalian brain, or for treating obesity *via* central POMC therapy. Thus, the present rejections under 35 U. S. C. § 103 fail the tripartite test established by the Court in *O'Farrell*, and therefore, are improperly applied against the pending claims.

Applicants further assert that any combination of the cited references is, at best, merely an invitation for further experimentation in the field, and at most, an "obvious-to-try" situation. However, there is *no* reasonable expectation of success, *nor* is there the motivation or teaching to guide a skilled artisan how to achieve such success. The Federal Circuit, in the case of *In re Geiger* (815 F.2d. 686, 2 U.S.P.Q.2d 1276, Fed. Cir. 1987), held that obviousness cannot be established by combining the teachings of the prior art to produce a claimed invention, absent some teaching, suggestion or incentive supporting the combination. Applicants therefore also believe that the present obviousness rejection fails the test set forth in *Geiger.*

Further, the Federal Circuit has affirmed that obviousness under 35 U. S. C. § 103 is a question of law, and that both the suggestion *and* the expectation of success must be founded in the prior art, and not in the Applicants' disclosure. *Amgen v. Chugai Pharmaceutical Co. Ltd.*, (927 F. 2d 1200, 18 U.S.P.Q. 2d 1016, 1022, Fed. Cir. 1991). Because the requisite suggestion and expectation of success are absent in the cited art, Applicants respectfully submit that the rejection also fails the test set forth in *Amgen v. Chugai Pharmaceutical Co. Ltd.*

2.5.1 THE REFERENCES ARE NOT PROPERLY COMBINABLE

In alleging that the invention is unpatentable over the cited references, the Action has taken Pritchard and/or Wilson together, or further in combination with either Lasic or Paterna2 to establish its a *prima facie* case of obviousness. Unfortunately, however, the Office appears to have ignored the legal standard governing the combination of references under 35 U. S. C. § 103.

It is well established, however, that before the Office may combine the disclosure of two or more prior art references in order to establish *prima facie* obviousness, there must be some *suggestion* for doing so, found either in the references themselves or in a knowledge generally available to one of skill in the art. *In re Fine*, 5 USPQ 2d 1596 (Fed. Cir. 1988). However, the range of sources available "does not diminish the requirement for actual evidence. That is, the showing must be clear and particular." *In re Dembiczak*, 50 USPQ 2d 1614, 1617 (Fed Cir. 1999).

The Appeals Court has also made it clear that "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references" (*In re Dembiczak*, *supra* at 1617). The Office must specifically identify "the reasons one of ordinary skill in the art would have been motivated to select the references and combine them" (*In re Rouffet*, 47 USPQ2d 1453, 1459 (Fed Cir. 1998). "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight" (*In re Dembiczak*, *supra* at 1617).

The Action therefore appears to look outside the cited references themselves to find the required suggestion to combine, but cites no source or authority as to the origin of the missing "suggestion to combine." To rely on "knowledge in the art" to suggest the combination of the cited

references, the Office is required to supply a convincing line of reasoning as to why the ordinary artisan would have found the claimed invention to have been obvious in light of the teachings of the cited references. *Ex parte Clapp*, 227 USPQ 972 (B.P.A.I. 1985).

Further, in cases in which the incentive to combine teachings of references is not readily apparent, it has been established that the Office must explain *why* such a combination of reference teachings is proper. *Ex parte Skinner*, 2 USPQ 1788 (B.P.A.I. 1986). "That knowledge *may* have been within the province of the ordinary artisan does not in and of itself make it so, absent clear and convincing evidence of such knowledge" (*Smiths Industries Medical Systems, Inc. v. Vital Signs Inc.*, 50 USPQ 2d 1641, 1646 (Fed. Cir. 1999).

Applicants submit that the incentive to combine the teachings of Pritchard and Wilson (in combination, or also further in view of the secondary references of Lasic or Paterna2) is *far* from readily apparent. Therefore, should the Office be motivated to maintain the present rejection, Applicants respectfully request that the Examiner explain the perceived suggestion to combine and support this by reference or affidavit, in accordance with 37 C. F. R. § 1.104(d)(2) and M. P. E. P. § 2144.03. Moreover, Applicants expressly reserve the right to challenge any such affidavit with evidence to the contrary in a future submission to the Office in accordance with 37 C. F. R. § 1.104(d)(2) (relying also on *In re Ahlert*, 165 USPQ 421 [C.C.P.A. 1970]).

2.5.2 PRITCHARD AND WILSON DO NOT OBVIATE THE CLAIMED INVENTION

On page 7 of the Official Action dated November 21, 2005 (hereinafter "Action of 11/21/05"), the Examiner noted that "Pritchard et al. teaches the use of MHC4, a mammalian POMC peptide that plays a role in the melanocortin pathway in the hypothalamus...Pritchard et al. also teaches the importance of the POMC-derived peptides as a potential research focus: "It is

becoming increasingly clear that many POMC-derived peptides and precursors are secreted in the hypothalamus and can activate melanocortin receptors."

The Action of 11/21/05 correctly recognized that "Pritchard does not teach the use of recombinant adeno-associated vectors." This is the key fact overlooked by the Office when concluding that Pritchard is proper as a primary reference in the rejections advanced over the reference in combination with the current secondary references.

The Examiner's own admission in the Action of 11/21/05 that Pritchard at best vaguely "discusses the importance of the POMC-derived peptides as a potential research focus," clearly evidences that the reference fails to provide the relevant teaching, suggestion, expectation of success, and motivation to combine with the secondary references to render the claimed invention obvious.

As Applicants previously noted in their Response to the Action of 11/21/05 (submitted February 21, 2006; hereinafter "Response of 2/21/06") Pritchard does not mention any type of viral vector compositions, and certainly does not mention AAV-based viral vector compositions. Likewise, Pritchard does not describe the construction of populations of rAAV viral particles comprising AAV vector constructs. Importantly, Pritchard does not mention the use of such rAAV vectors to transfect any mammalian host cells. It also does it teach or suggest the use of any diagnostic or therapeutic kits that comprise rAAV-based vectors. Finally, the reference does not mention that such vectors may be used to deliver mammalian POMC-encoding nucleic acid segments to mammalian host cells, or for expressing such vector constructs in mammalian hosts.

While Pritchard concludes that POMC has a role in obesity (based upon their observations that animals and humans who have deficiencies in the POMC gene are frequently obese), and that pharmacologic manipulation of POMC processing (*e.g.*, transcriptional,

translational, or posttranslational proteolytic processing) might be exploited for treating such obese animals, Pritchard provides no suggestion that a viral vector-delivered gene therapy approach to treating these would be successful. Nor does the reference suggest that obese animals might respond to central delivery of POMC-encoding rAAV-vectors. Because native POMC polypeptide needs to be processed to yield the biologically-active peptide (α-MSH), the present inventors recognized that any treatment regimens for obesity involving *systemic* delivery of POMC polypeptide would be an impractical and technically limited.

The addition of Wilson as a secondary reference to Pritchard also fails to advance a credible argument against patentability of the claimed invention, since, by the Examiner's own admission, Wilson is a generic teaching that provides a number of rAAV *serotype 1* vector constructs for delivery of nucleic acid segments to mammalian cells. In particular, Wilson discusses rAAV serotype 1 vectors useful in delivery of α_1-antitrypsin-encoding polynucleotides. Wilson does not teach or suggest vectors for the delivery of POMC-encoding polynucleotides, nor does it provide a method of using POMC-encoding vector compositions in treatment of obesity. The Wilson reference also does not provide the requisite suggestion that the disclosure of Pritchard could be modified to achieve the present invention without undue experimentation.

In light of these reasons, the rejection over Pritchard in view of Wilson should be withdrawn.

2.5.3 LASIC FAILS TO PROVIDE A REASONABLE EXPECTATION OF SUCCESS

The combination of Pritchard and Wilson with the secondary reference by Lasic also fails to provide the requisite reasonable expectation of success in order to obviate the claimed rAAV-POMC vector compositions and/or their use in the treatment of obese mammals. The

combination of Pritchard, Wilson, and Lasic does not provide the reasonable expectation of success that the skilled artisan would be able to develop such rAAV vector compositions, particularly since Lasic neither teaches nor suggests the use of rAAV vectors that express one or more nucleic acid segments encoding a POMC polypeptide.

While Lasic provides information for the packaging of bioactive compounds by means of liposomes and microspheres, it certainly does not teach or suggest the use of such liposomes and/or microspheres as a means of delivering rAAV vector compositions (and in particular, POMC-encoding rAAV vector constructs) to a mammal. Lasic also fails to teach of suggest the use of liposomes and microspheres to prepare pharmaceutical formulations of the claimed rAAV-POMC vectors for use in human therapy. Likewise, consideration of Pritchard and Wilson in further view of Lasic also fails to teach or suggest the use of the Lasic liposomes or microspheres as a means of directly delivering rAAV-POMC gene therapy vectors to one or more regions of a human brain.

Applicants respectfully request, therefore, that in light of these shortcomings, the rejection over Pritchard and Wilson further in view of Lasic should also be withdrawn.

2.5.4 PATERNA2 ALSO FAILS TO PROVIDE A REASONABLE EXPECTATION OF SUCCESS

The combination of Pritchard and Wilson with the disclosure in Paterna2 also does not provide the requisite *prima facie* case sufficient to obviate the claimed invention.

The Action at pages 10-11 states that "Paterna et al. teaches the use of post transcriptional regulatory element WPRE in rAAVs as a means to enhance in vivo transgene expression....(o)ne of ordinary skill in the art at the time the invention was made would have been motivated to combine the POMC peptide of Pritchard et al and the adeno-associated viral vector of Wilson et

al. and the WPRE of Paterna(2) et al., because Paterna(2) et al. teaches that incorporation of the WPRE into the rAAV vectors enhances transgene expression in vivo."

The Action further states that "One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for using the pro-opiomelanocortin peptide of Pritchard et al. and the recombinant adeno-associate vector of Wilson et al. and the WPRE of Paterna et al. because all teach or suggest methods of gene therapy using peptides and rAAV vectors encoding genes encoding peptides."

Applicants respectfully traverse.

First, Applicants note that the claimed rAAV vectors do not "encode" genes. The present invention employs rAAV vectors that comprise at least a first nucleic acid segment that encodes *a POMC polypeptide* but the claimed vectors do not encode any genes.

Second, Applicants disagree with the Office's statement that "all (four) references teach or suggest methods of gene therapy and rAAV vectors." In fact, neither Lasic nor Pritchard even mention gene therapy or rAAV vectors, and most certainly do not teach or suggest any rAAV-POMC genetic constructs that could be useful in treatment of a mammal.

Third, Paterna2, while discussing the effects of promoters and post-transcriptional regulatory elements on AAV-mediated transgene expression in the rat brain, the reference says nothing about the use of such promoters or regulatory elements to alter the expression of a rAAV-based gene construct that encodes a biologically-active POMC polypeptide.

Since the rejection over Pritchard and Wilson further in view of Paterna2 fails the requisite three-prong requirement for obviousness as set forth in *O'Farrell*, Applicants therefore respectfully request that it now be withdrawn.

2.5.5 THE INVENTION IS PATENTABLE OVER THE CITED REFERENCES

In sharp contrast to the prior art, the present inventors have shown that a *single injection* of rAAV-POMC vector to the brain of a mammalian model of obesity resulted in responses that lasted *at least 45 days* in one study[2] and *at least 80 days* in another (See **Exhibit A**, FIG. 1 attached). Both of these studies were terminated *before the responses attenuated*, thus the true maximum duration of a single treatment with rAAV-POMC has yet to be determined. In fact, the inventors contemplate that the effect of a single injection could extend well beyond the 80-day mark, and that sequential administration of the POMC composition could significantly prolong the duration of therapeutic benefit from several weeks, to several months or more.

The surprising and unexpected prolonged nature of this response could not have been predicted from Pritchard (either alone or in combination with Wilson, Lasic, or Paterna2), because Pritchard contained no suggestion that the claimed rAAV vector-based delivery of POMC-encoding polynucleotides would provide a superior long-term treatment of mammalian obesity. The long-term therapeutic results obtained by Applicants using the disclosed rAAV-POMC compositions would certainly not have been predicted from the teachings of Pritchard (either alone or in combination with one of the secondary references), since Pritchard achieved only *very* short-term (less than one week!) results when administering α-MSH peptides to control obesity in their rodent model of the disease, and each of the secondary references is completely silent about the therapeutic potential for rAAV-vectored POMC-encoding genetic constructs in the management or treatment of obesity.

[2]Li, G., Zhang, Y., Wilsey, JT, and Scarpace, PJ, "Hypothalamic pro-opiomelanocortin gene delivery ameliorates obesity and glucose intolerance in aged rats," *Diabetologia,* **48**:2376-2385, (2005).

2.5.6 APPLICANTS' RESULTS HAVE BEEN SUBSTANTIATED BY THIRD-PARTY, POST-FILING REPORTS

Subsequent to the present invention, Applicants have learned that two independent groups of third-party researchers have confirmed (through completely separate experimentation) the surprising results as first reported by the present inventors. Whereas the present inventors utilized gene delivery to directly administer rAAV-POMC to an otherwise normal animal, the two recent reports achieved overexpression of the POMC gene by altering the genome of mice to produce a transgenic mouse model that overexpressed the POMC gene. Their findings (while achieved through different genetic manipulation techniques), nevertheless substantiated the original reports by Applicants that delivery of POMC-encoding polynucleotides to a recipient animal could result in marked weight reduction in obese animals.

In the first of these very recent studies[3], Mizuno *et al.* demonstrated a weight-reducing effect for 16 weeks as a result of POMC overexpression in the transgenic mouse. The second of these reports[4] also utilized a transgenic mouse that overexpressed POMC gene, and demonstrated a reduced body weight for at 25 days. Both of these studies were terminated before any attenuation of the response was noted, so it is not known where the true endpoints of the study may have been. Their results, however, clearly substantiated the fundamental teachings outlined by the inventors in the present Application.

In conclusion, for the aforementioned reasons Applicants respectfully request that the obviousness rejections be withdrawn for all pending claims, and that the Application now proceed to rejoinder of the non-elected inventions.

---

[3]Mizuno TM, Kelley KA, Pasinetti GM, Roberts JL, and Mobbs CV, "Transgenic neuronal expression of proopiomelanocortin attenuates hyperphagic response to fasting and reverses metabolic impairments in leptin-deficient obese mice," *Diabetes,* **52**(11):2675-8 (November, 2003).

[4]Savontaus E, Breen TL, Kim A, Yang LM, Chua SC Jr, and Wardlaw SL, "Metabolic effects of transgenic melanocyte-stimulating hormone overexpression in lean and obese mice," *Endocrinol.,* **145**:3881–3891 (August, 2004).

2.6 APPLICANTS REQUEST REJOINDER OF THE NON-ELECTED INVENTIONS UPON ALLOWANCE OF THE ELECTED INVENTION

Applicants note for the record that under the current Statutes, and consistent with the C. F. R., the M. P. E. P, and Technology Center 1600 restriction training materials, when compositions of a restriction group are elected for initial prosecution on the merits, then the subject matter of the non-elected invention(s) (*e.g.*, the Group II invention, directed to *methods of using the compositions of Group I*), is subject to rejoinder upon the allowance of the corresponding composition claims. As such, Applicants again state their affirmative intention to seek rejoinder of the "process for using" claims upon allowance of claims directed to the products claimed in the Group I invention. Referring to the pertinent part of M. P. E. P. § 821.04(b):

> "Where claims directed to a product and to a process of making and/or using the product are presented in the same application, applicant may be called upon under 35 U. S. C. § 121 to elect claims to either the product or a process....(T)he claims to the non-elected inventions will be withdrawn from further consideration under 37 C. F. R. § 1.142....*(H)owever, if applicant elects a claim(s) directed to a product which is subsequently found allowable, withdrawn process claims which depend from or otherwise require all the limitations of an allowable product claim will be considered for rejoinder.* All claims directed to a non-elected process invention must depend from or otherwise require all the limitations of an allowable product claim for that process invention to be rejoined. Upon rejoinder of claims directed to a previously non-elected process invention, the restriction requirement between the elected product and rejoined process(es) will be withdrawn." (emphasis added).

Thus, by constructive election of the products of the Group I invention for initial prosecution on the merits, Applicants again affirmatively state their intention of requesting proper rejoinder of claims directed to a process of using such compositions (*i.e.*, the subject matter of the Group II invention) upon allowance of the subject matter of the Group I invention.

2.7 REQUEST FOR EXAMINER INTERVIEW

Pursuant to M. P. E. P. § 713.01 and 37 C. F. R. § 1.133, Applicants hereby request an interview with Applicants' undersigned representative in order to facilitate an expeditious conclusion of prosecution on the merits in the present application, and to permit expedited allowance and issuance of the pending claims.

Consistent with M. P. E. P. §§ 408 and 713.09, Applicants request that Examiner Salvoza contact the undersigned representative as soon as he has received and considered the present submission (preferably within the next 30 days), and *prior to the issuance of a subsequent action on the merits* to schedule an Examiner Interview at a mutually convenient time.

2.8 CONCLUSION

It is respectfully submitted that all claims are fully enabled by the Specification, and that all claims are definite and free of the prior art. Applicants believe that the claims are acceptable under all sections of the Statutes and are now in conditions for ready allowance, and that all of the concerns of the Examiner have been resolved. Applicants earnestly solicit concurrence by the Examiner and the issuance of a Notice of Allowance in the case with all due speed.

Applicants note for the record their explicit right to re-file claims to one or more aspects of the invention as originally claimed in one or more continuing application(s) retaining the priority claim from the present and parent cases.

As always, should Examiner Salvoza have any questions or require any additional information, a telephone call to the undersigned Applicants' representative would be welcomed.

Respectfully submitted,

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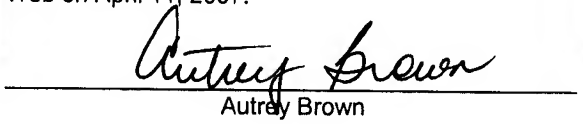

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Exhibit A

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